Amount of Total Related Substances at Various Stages of Manufacturing

	1	2	3	4	5	6
Key Ingredient	Monothio-glycerol	Citrate Buffer pH 3.5	Citrate Buffer pH 5	Acetate Buffer pH 3.6	Lyophilized using Mannitol	Lyophilized using Lactose
Unautoclaved	0.13	0.12	0.16	0.20	0.14	0.12
Autoclaved	0.91	0.23	0.61	1.39	n/a	n/a
Stability (2 mths at room temp)	1.10	0.16	0.48	1.26	0.15	0.15

It should be understood that various changes and modifications to the preferred embodiments described herein will be apparent to those of ordinary skill in the art. Such changes and modifications can be made without departing from the spirit and scope of this invention without diminishing its advantages. It is therefore intended that such changes and modifications, including equivalents, be covered by the appended claims. All of the patents, patent applications and references listed herein are incorporated by to reference in their entirety.

The invention claimed is:

1. A stable pharmaceutical preparation comprising a solution of methylnaltrexone or a salt thereof, wherein the preparation comprises a pH between about 3.0 and about 4.0.

2. The pharmaceutical preparation of claim **1**, wherein the pH is about 3.0 to about 3.5.

3. The pharmaceutical preparation of claim **1**, wherein the concentration of methylnaltrexone or salt thereof ranges from 0.01 to 100 mg/ml.

4. The pharmaceutical preparation of claim **1**, wherein the concentration of methylnaltrexone or salt thereof ranges from 1.0 to 50.0 mg/ml.

5. The pharmaceutical preparation of claim **1**, wherein the concentration of methylnaltrexone or salt thereof is about 20 mg/ml.

6. The pharmaceutical preparation of claim **1**, wherein the preparation is stable to storage for 6 months at about room temperature.

7. The pharmaceutical preparation of claim **1**, wherein the preparation is stable to storage for 12 months at about room temperature.

8. The pharmaceutical preparation of claim **1**, wherein the preparation is stable to storage for 24 months at about room temperature.

9. The pharmaceutical preparation of claim **1**, further comprising a preservative.

10. The pharmaceutical preparation of claim **4**, further comprising a preservative.

11. The pharmaceutical preparation of claim **1**, further comprising an isotonicity agent.

12. The pharmaceutical preparation of claim **4**, further comprising an isotonicity agent.

13. The pharmaceutical preparation of claim **1**, wherein the preparation is suitable for parenteral administration.

14. The pharmaceutical preparation of claim **13**, wherein the solution is provided in a vial with a septum or in a syringe.

15. The pharmaceutical preparation of claim **6**, further comprising a preservative.

16. The pharmaceutical preparation of claim **6**, further comprising an isotonicity agent.

17. The pharmaceutical preparation of claim **6**, wherein the preparation is suitable for parenteral administration.

18. A pharmaceutical preparation comprising a solution of methylnaltrexone or a salt thereof, wherein the preparation has a pH ranging from 3.0 to 4.0, wherein the preparation is stable to storage for 6 months at about room temperature and wherein the preparation is suitable for parenteral administration.

19. The pharmaceutical preparation of claim **18**, further comprising a preservative.

20. The pharmaceutical preparation of claim **18**, further comprising an isotonicity agent.

21. The pharmaceutical preparation of claim **18**, wherein the preparation has a pH of about 3.5.

22. The pharmaceutical preparation of claim **18**, wherein the preparation has a pH of about 3.0 to about 3.5.

23. The pharmaceutical preparation of claim **1**, wherein the preparation has a pH of about 3.5.

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